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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BLATT, ERIC D	

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3709	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,886	DORN, JURGEN	
	Examiner	Art Unit	
	Eric Blatt	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

KHOI H. TRAN
SUPERVISORY PATENT EXAMINER

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-10-2006, 12-12-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Acknowledgement is made that the present application is a national stage entry of PCT/EP04/04486 filed April 28, 2004.

Response to Amendment

Acknowledgement is made of the Preliminary Amendment filed July 5, 2006 amending claim 11 and adding claims 21-32.

Claim Objections

Claim 28 is objected to because of the following informalities: claim 28 indefinitely recites "a stent" where a stent has previously been recited in the claim. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-29 of copending Application No. 10/572191. Although the conflicting claims are not identical, they are not patentably distinct from each other because their claimed inventions are substantially identical. While there are subtle variations in the limitations claimed, these differences would have been obvious to one of ordinary skill in the art at the time of the invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrea et al. (US 2002/0038143) in view of Grosjean et al. (US 5,619,878).

Regarding claims 1-9 and 19-22, McCrea discloses a method of loading a self-expanding stent into a delivery sheath, comprising:

- providing said self-expanding stent as a covered stent having a stent matrix with surfaces defining luminal and abluminal envelopes spaced apart by a stent wall thickness, a covering layer positioned on a luminal wall surface comprising a covering material bonded to the matrix lying radially inside the luminal envelope (Paragraphs 73-76)
- providing a stent pusher (the stainless steel mandrel is interpreted as a stent pusher) in a lumen defined by the stent,
- compressing the stent radially inwardly (Paragraphs 73-76)

For this embodiment, McCrea does not disclose:

- advancing the stent into the sheath.

For multiple other embodiments of the method disclosed within McCrea, a stent is advanced into a sheath to prevent the stent from expanding prior to reaching its delivery site. The embodiment disclosed in paragraphs 73-76 contains an elastic self-expanding stent, but the stent is constrained from prematurely expanding to its larger diameter by the stiffness of a thin layer of ePTFE alone. (Paragraphs 73-76) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the present method of McCrea by adding the step of advancing the stent into a sheath for purposes such as ensuring the stent does not expand prior to reaching its intended delivery site in the event that the ePTFE should fail to prevent such a premature expansion.

Additionally, McCrea does not disclose:

- the stent pusher having helically arranged protrusions distributed along the distal end there of and along the length of the stent lumen;
- the protrusions deform the covering material but do not reach radially outwardly far as the luminal envelope

Grosjean discloses that it is old and well known in the art to provide helically arranged protrusions about the surface of a pusher/mandrel in order to ease removal of the pusher/mandrel by allowing it to be unscrewed. (Figures 1-4, Column 5, Lines 48-65) It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of McCrea by providing the pusher with helically arranged protrusions and upon placement of the stent, withdrawing the pusher by unscrewing it from the covering layer. Since the covering layer is pressed tightly against the pusher, the protrusions would deform the covering material but would not reach radially outwardly as far as the luminal envelope. Additionally, upon loading the stent into the sheath, an endwise force would be imposed on the stent pusher so that the covering material would transfer the pushing force from the protrusions of the stent pusher to the stent matrix to advance the stent into the sheath.

Claims 3-18 and 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemerick et al. (US 7,011,675) in view of Barth et al. (US 4,576,534).

Regarding claim 3, Hemerick discloses a delivery system (Figure 5) including a self-expanding stent 102 in a percutaneous transluminal delivery catheter that includes a

sheath 105 that withdraws proximally to release the stent at a stenting site, comprising:

- a pusher 104b within the sheath that extends along the lumen of the stent
- the stent being a covered stent (Column 8, Lines 27-32) having a matrix with surfaces defining luminal and abluminal envelopes spaced apart by a stent wall thickness, a covering material bonded to the matrix lying radially inside the luminal envelope

Hemerick does not disclose

- the pusher having radially outwardly extending protrusions distributed along the length of the lumen
- the stent being positioned over the protrusions such that the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope.

The stent of Hemerick is deployed by retracting the outer sheath 105c while keeping the pusher 104b stationary. (Column 1, Lines 11-29) Thus, it is important that the stent does not move relative to the pusher 104b during deployment. To this end, the pusher includes a thickened portion 104c that frictionally engages with the stent. (Figures 5a-5b) Barth discloses that it is old and well known in the art to provide radially outwardly helical protrusions on a surface to increase that surface's ability to frictionally engage a second surface. (Figures 1-4, See Abstract) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Hemerick by providing radially outwardly helical protrusions on the pusher 104b, specifically on the thickened portion 104c for purposes such as increasing the frictional engagement between the pusher and the stent during

deployment as taught by Barth. These protrusions would deform the covering material but would not reach radially outwardly as far as the luminal envelope.

- Regarding claim 7, said protrusions are the turns of a spiral.
- Regarding claim 9, there is a tapered distal tip 117 on said pusher, distal of said sheath. (Figures 5a-5b)

Regarding claim 10, Hemerick discloses a delivery system, comprising:

- a self-expanding stent 102 having a wall and a luminal and abluminal wall surface, a first covering layer positioned on at least the luminal wall surface; (Column 8, Lines 27-32)
- an outer sheath 105 having a distal end configured to receive and maintain the stent in a reduced diameter delivery configuration; and
- an inner catheter 104b having a distal end positioned within a lumen of the stent

Hemerick does not disclose

- the inner catheter including radially outwardly extending protrusions along the distal end that extend into the covering without intersecting a plane along the luminal wall surface.

The stent of Hemerick is deployed by retracting the outer sheath 105c while keeping the pusher 104b stationary. (Column 1, Lines 11-29) Thus, it is important that the stent does not move relative to the pusher 104b during deployment. To this end, the pusher includes a thickened portion 104c that frictionally engages with the stent. (Figures 5a-5b) Barth discloses that it is old and well known in the art to provide radially outwardly helical protrusions on a surface to increase that surface's ability to frictionally engage a second surface. (Figures 1-4, See Abstract) It would have

been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Hemerick by providing radially outwardly helical protrusions on the pusher 104b, specifically on the thickened portion 104c for purposes such as increasing the frictional engagement between the pusher and the stent during deployment as taught by Barth. These protrusions would extend into the covering without intersecting a plane along the luminal wall surface.

- Regarding claim 13, the delivery system further comprises a plurality of markers 131. (Figures 5a-5b, Columns 8-9)
- Regarding claim 14, the markers are arranged circumferentially about a proximal and distal end of the stent. (Figures 5a-5b, Columns 8-9)
- Regarding claim 15, the protrusions taught by Barth are formed by a thin metallic element arranged helically about and bonded to an inner shank. This element is interpreted as a wire. Thus, the protrusions of the modified device are formed by a wire arranged helically about and bonded to the inner catheter.
- Regarding claim 21, the pusher has an outside diameter smaller than a luminal diameter of the stent. (Figure 5a)
- Regarding claim 23, the inner catheter comprises a material selected from the group consisting of stainless steel, flexible polymer, and combinations thereof. (Column 7, Lines 37-63)
- Regarding claim 24, the inner catheter defines a guidewire lumen. (Column 5, Lines 34-62)
- Regarding claim 26, the markers are comprised of tantalum. (Column 8, Lines 8-64)

Regarding claim 28, Hemerick discloses a method of deploying a stent comprising:

- providing a delivery system including a stent 102 loaded in a reduced diameter configuration between an inner catheter 104b and an outer sheath 105, the stent including a covering positioned on a luminal wall surface thereof (Column 8, Lines 27-33)
- advancing the delivery system to a stenting site (Column 1, Lines 11-29); and
- withdrawing the outer sheath to deploy the stent at the stenting site. (Column 1, Lines 11-29)

Hemerick does not disclose

- the inner catheter including radially outwardly extending protrusions that extend into the covering.

The stent of Hemerick is deployed by retracting the outer sheath 105c while keeping the pusher 104b stationary. (Column 1, Lines 11-29) Thus, it is important that the stent does not move relative to the pusher 104b during deployment. To this end, the pusher includes a thickened portion 104c that frictionally engages with the stent. (Figures 5a-5b) Barth discloses that it is old and well known in the art to provide radially outwardly helical protrusions on a surface to increase that surface's ability to frictionally engage a second surface. (Figures 1-4, See Abstract) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Hemerick by providing radially outwardly helical protrusions on the pusher 104b, specifically on the thickened portion 104c for purposes such as increasing the frictional engagement between the pusher and the stent during deployment as taught by Barth. These protrusions would extend into the covering.

- Regarding claim 29, the withdrawing includes a tip of the outer sheath stretching and sliding over an abluminal wall surface of the stent.
- Regarding claim 30, the withdrawing includes withdrawing the outer sheath by moving a proximal end of the outer sheath in a proximal direction. (Column 1, Lines 11-29)
- Regarding claim 32, Hemelick further discloses withdrawing the inner catheter from the lumen of the stent graft following expansion thereof to an expanded diameter. (Column 3, Lines 9-21)

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemerick et al. (US 7,011,675) in view of Barth et al. (US 4,576,534) as applied to claim 3 above and further in view of McCrea et al. (US 2002/0038143).

Regarding claims 4-6, all elements of claims 4-6 are disclosed by Hemerick in view of Barth as previously discussed except:

- the stent matrix comprising metal and the covering comprising expanded polytetrafluoroethylene
- the stent matrix being apertured and the covering being bonded to an abluminal stent covering layer through the apertures; and
- the stent matrix being formed from a nickel-titanium shape memory alloy.

While a Hemerick does not disclose a stent meeting these limitations, Hemerick does disclose that the apparatus disclosed within may be used for deploying a stent "that typically is maintained in a stressed, compressed, and elongated state within [a

sheath]." (Column 5, Lines 1-5) McCrea discloses a stent that is typically maintained in a stressed, compressed, and elongated state within a sheath wherein

- the stent matrix comprises metal and the covering comprising expanded polytetrafluoroethylene
- the stent matrix is apertured and the covering is bonded to an abluminal stent covering layer through the apertures; and
- the stent matrix is formed from a nickel-titanium shape memory alloy.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the stent disclosed in McCrea for the stent disclosed in Hemerick since they were known alternatives at the time of the invention and their substitution would not have produced unexpected results.

Claims 11-12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemerick et al. (US 7,011,675) in view of Barth et al. (US 4,576,534) as applied to claim 10 above and further in view of McCrea et al. (US 2002/0038143).

Regarding claims 11-12 and 18, all elements of claims 11-12 and 18 are disclosed by Hemerick in view of Barth as previously discussed except:

- a second covering layer on the abluminal surface of the stent, wherein the first covering layer is bonded to the fi-wA second covering layer through apertures in the stent wall
- the first and second covering layers are comprised of ePTFE; and
- stent is cut from a nickel-titanium tube.

While a Hemerick does not disclose a stent meeting these limitations, Hemerick does disclose that the apparatus disclosed within may be used for deploying a stent "that typically is maintained in a stressed, compressed, and elongated state within [a sheath]." (Column 5, Lines 1-5) McCrea discloses a stent that is typically maintained in a stressed, compressed, and elongated state within a sheath wherein

- a second covering layer on the abluminal surface of the stent, wherein the first covering layer is bonded to the fi-wA second covering layer through apertures in the stent wall
- the first and second covering layers are comprised of ePTFE; and
- stent is cut from a nickel-titanium tube.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the stent disclosed in McCrea for the stent disclosed in Hemerick since they were known alternatives at the time of the invention and their substitution would not have produced unexpected results.

Claims 16, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemerick et al. (US 7,011,675) in view of Barth et al. (US 4,576,534) as applied to claims 10 and 15 above and further in view of Healy et al. (US 6,613,075).

Regarding claims 16 and 27 all elements of claims 16 and 27 are disclosed by Hemerick in view of Barth as previously discussed while addressing claim 15 except:

- the inner catheter is comprised of stainless steel
- the wire is comprised of stainless steel.

Healy discloses a delivery system in which:

- an inner catheter is comprised of stainless steel (Column 8, Lines 1-5)
- a wire is comprised of stainless steel. (Column 6, Lines 30-42)

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus disclosed by Hemerick in view of Barth by having the inner catheter comprise stainless steel for purposes such as structurally reinforcing the inner catheter as taught by Healy. Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus disclosed by Hemerick in view of Barth by having the wire comprise stainless steel for purposes such as using a widely available biocompatible material.

Regarding claim 25, all elements of claim 25 are disclosed by Hemerick in view of Barth as previously discussed while addressing claim 10 except:

- wherein the delivery system comprises a rapid exchange system with the guidewire lumen only in a distal zone of the delivery system.

Healy discloses a delivery system comprising a rapid exchange system with the guidewire lumen only in a distal zone of the delivery system. (Figures 1-3, Column 5, Line 56 to Column 6, Line 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus disclosed by Hemerick in view of Barth by providing a rapid exchange system with a guidewire lumen only in a distal zone of the delivery system for purposes such as allowing the catheter to be removed and exchanged without removing the guidewire.

Claims 8, 17, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemerick et al. (US 7,011,675) in view of Barth et al. (US 4,576,534) as applied to claims 3 and 10 above and further in view of Dehdashtian et al. (US 6,143,014).

Regarding claims 8, 17, and 22, all elements of claims 8, 17, and 22 are disclosed by Hemerick in view of Barth as previously discussed while addressing claims 3 and 10 except:

- the outer sheath includes a tapered distal tip
- wherein the tapered distal tip narrows to an end ring of a diameter appropriate to receive a guidewire.

Dehdashtian discloses a delivery system comprising an outer sheath including a tapered distal end wherein the tapered distal tip narrows to an end ring of a diameter appropriate to receive a guidewire. (Figures 10a-10h, Column 7, Lines 62-67) It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus disclosed by Hemerick in view of Barth by providing the sheath with a tapered distal tip wherein the tapered distal tip narrows to an end ring of a diameter appropriate to receive a guidewire for purposes such as facilitating navigation through body lumens.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hemerick et al. (US 7,011,675) in view of Barth et al. (US 4,576,534) as applied to claim 28 above and further in view of Eder et al. (US 6,585,753).

Regarding claim 31, all elements of claim 31 are disclosed by Hemerick in view of Barth as previously discussed except:

- withdrawing the outer sheath includes using a pull wire within a shaft lumen to proximally move the outer sheath.

Eder discloses a method of deploying a stent comprising withdrawing an outer sheath by using a pull wire within a shaft lumen to proximally move the outer sheath. (Figure 4, Column 8, Lines 1-13) It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the method of withdrawing the outer sheath disclosed in Eder for the method of withdrawing the outer sheath disclosed in Hemerick since they were known alternatives at the time of the invention and their substitution would not have produced unexpected results.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents disclose relevant designs and methods:

Hijlkema; Lukas J. et al.	US 6858034 B1
Sullivan, Jason R. et al.	US 20040106977 A1
Rourke, Jonathan M. et al.	US 20020193863 A1
Sullivan; Jason R. et al.	US 6607551 B1
Yee, Carl E.	US 20020029076 A1
Marin; Michael L. et al.	US 5697948 A
Seyler; Paul R. et al.	US 20060216404 A1

Stallings; Jody W. et al.	US 6776791 B1
Morales; Stephen A.	US 5920975 A
Gianturco; Cesare	US 4580568 A
Landau, George D. et al.	US 20020058993 A1
EDWIN, TARUN J. et al.	US 20010039446 A1
Karmon; Ben-Zion	US 20070156251 A1
McCrea; Brendan J. et al.	US 6758858 B2
McCrea; Brendan J. et al.	US 6451047 B2
Banas; Christopher E. et al.	US 6214039 B1
Huang, Mark	US 20030032999 A1
Shin; Mark Young	US 6063092 A
Klein; Enrique J. et al.	US 5776141 A
Austin; Michael	US 20060184226 A1
Banas; Christopher E. et al.	US 5749880 A
Pletzer, Scott et al.	US 20020147490 A1
Betelia; Rainier et al.	US 6945989 B1
Staehle; Bradford G. et al.	US 6471718 B1
Khan; I. John et al.	US 5928258 A
Pryor; Jack	US 20060184225 A1
Schaldach; Max et al.	US 6796998 B2
Gunderson, Richard	US 20040204749 A1
Thompson; Richard J. et al.	US 5876448 A

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571) 272-9735. The examiner can normally be reached on Monday to Friday, 7:30 A.M. to 5:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Khoi Tran can be reached on (571) 272-6919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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